EXHIBIT 2

Declaration of Manoj Misra with Exhibits A-E

DECLARATION OF DR. MANOJ MISRA

- I, Manoj Misra, Ph.D., hereby declare as follows:
- 1. I have been engaged by Defendants to provide assistance and advice in the matter of Bidi Vapor, LLC v. Vaperz LLC, et al., 1:21-cv-01430, which is pending in the United States District Court for the Northern District of Illinois.
- 2. I am over the age of 18. The following facts are within my personal knowledge.
- 3. I am being compensated at an hourly rate of \$500. My compensation is not contingent on my assistance/advice or the result in the litigation.
- 4. My resume is attached as **Exhibit A**. I have extensive experience in the tobacco and ecigarette industries. I have worked for years for many leading companies in these industries. My roles have included dealing with toxicology assessments of product ingredients, regulatory requirements, and risk and safety assessments. In my work experience, I have advised companies on how to properly advertise various ingredient concentrations and levels, including nicotine concentrations.
- 5. I am familiar with both MNGO Sticks and Bidi Sticks.
- 6. I am aware that this lawsuit raises false advertising claims based on Defendants' advertising MNGO Stick as "6% nicotine."
- 7. In my opinion, the MNGO Sticks at issue in this case are in line with standard industry practices and their claim of a 6% nicotine product, as advertised, and MNGO Stick's advertised nicotine content is accurate and not misleading to a common consumer based at least on the same industry standard that Bidi Vapor, LLC is following (as advertised on their labeling and website).
- 8. I reviewed laboratory tests from Shenzhen Alpha Product Testing Co., Ltd ("Alpha") conducted on March 11, 2021 following standard AFNOR XP D90-300-2:2015. [Attached as

- **Exhibit B**]. I am familiar with this standard and it is an acceptable standard for identifying nicotine concentration. I have been informed that these test results were ordered by the manufacturer and performed on a random sampling of MNGO Sticks made in early March of 2021.
- 9. The average result of the March 11, 2021 testing was a nicotine concentration of 48.96 mg/g. It is accurate to refer to this result as a percentage of 4.896% nicotine by weight.
- 10. It is also accurate to report nicotine amounts as a combination of weight / volume. In fact, based on my review of Bidi's packaging, Bidi reports a nicotine percentage as well as a weight / volume amount and follows others in the industry by stating this weight / volume amount as a percent.
- 11. Converting the Alpha report's weight concentration to weight / volume involves multiplying the weight concentration by the specific gravity of the e-liquid, which I have been informed is about 1.12 g/mL.
- 12. The result of the conversion indicates the tested MNGO Stick sample has an average nicotine concertation of 54.84 mg/mL. and exhibits on average 5.38% nicotine by volume assuming a 1.02 mg/mL specific gravity of nicotine.
- 13. Alpha also performed another set of tests on April 13, 2021. These tests were ordered by the manufacturer of the MNGO Stick to determine whether product samples produced in April 2021 meet manufacturing specifications. The results of these tests indicate an average nicotine concentration of 54.81 mg/mL and exhibits on average 5.37% nicotine by volume assuming a 1.02 mg/mL specific gravity of nicotine. [Exhibit C].
- 14. I reviewed the relevant portions of the manufacturing specifications for MNGO stick as it relates to nicotine concentration which I understand were provided to Defendants. [Exhibit D]. The manufacturing specification indicates a nicotine concentration of 53 mg/mL with deviations

- of \pm 10% at lot release and \pm 10% and \pm 35% at end point. As explained in more detail below, nicotine is known to degrade over time, leading to the relatively low bounds of the end point range.
- 15. The results of both sets of tests by Alpha demonstrates MNGO Stick is within the tolerances set by the manufacturer because the actual nicotine concentration at release of 54.84 mg/mL (March 2021) and 54.81 (April 2021) is within the range of 47.7 mg/mL to 58.3 mg/mL.
- 16. In my experience, manufacturing specifications are typically slightly lower than the advertised nicotine concentration but are still accurately advertised as being nicotine products of the advertised amount here, a 6% nicotine product. I am unaware of the FDA ever issuing a recall based on nicotine content being below an advertised amount.
- 17. I believe the tolerances and specifications set by the manufacturer of MNGO Stick are reasonable and in-line with industry and consumer expectations.
- 18. The FDA does not currently have set tolerances for advertised nicotine concentrations, nor does the FDA set manufacturing specifications for products. Rather, with respect to advertising requirements, the FDA defers to manufacturer specifications.
- 19. I am aware that Bidi had a number of MNGO Sticks tested and the average nicotine concentration of 3.22% by weight. I have reviewed those results. Following the above conversions, this equates 36.1 mg/mL and a nicotine concentration of 3.54% by volume.
- 20. These test results do not indicate that the MNGO Stick is falsely representing a 6% nicotine concentration. Based on my experience, it is likely that the main factor contributing to these results is nicotine degradation.
- 21. Nicotine is a relatively unstable substance and is known to degrade over time. Since I do not know the age of the product tested by Bidi, the natural degradation of nicotine could explain the low test results. Over my career, I have observed and/or studied various effects of external

factors on nicotine degradation as summarized in a document I authored entitled "Nicotine Loss Summary" attached hereto. In general, the degradation of nicotine over time may be accelerated by exposure to water, heat, light, oxidation caused by exposure to UV light, acids, hydrogen peroxide, chlorine, and metal. Further, nicotine stability and degradation are affected by the purity of the nicotine used, packaging factors such as oxygen transfer rate, and by storage conditions. Since I do not know how the product tested by Bidi was handled, its degradation could have been accelerated. Additional detail on these degradations can be found in the document attached as **Exhibit E**.

- 22. I have reviewed a report from Legend Technical Services, Inc., which reports the nicotine concentration of a number of products competitive with MNGO Stick, including the Bidi Stick.
- 23. The average nicotine concentration of the tested Bidi Stick was 4.99% by weight and 5.47% by volume, assuming a specific gravity of the e-liquid of 1.12 g/mL. While the Bidi Stick's manufacturing specifications are not available to me, nor do I know the specific gravity of the Bidi Stick's e-liquid, the actual nicotine concentration of 5.47% by volume is in-line with what I understand to be commonplace for products advertised as containing 60 mg/mL. It is also in line with the MNGO Stick's nicotine concentration.
- 24. Based on my experience in this industry, normal manufacturing variations result in an actual nicotine concentration for freshly made products within about 15% below an advertised percentage, and this is reasonable, acceptable, commonplace in this industry, and in-line with industry and consumer expectations.
- 25. Turning to the MNGO Stick, the testing results provided to me by Defendants demonstrate that the actual nicotine in the MNGO Stick (5.37% in March 2021 and 5.38% in April 2021) is within about 10% of the advertised 6% nicotine, which is within its specifications and

commonplace advertising practices in this industry. Again, I base my belief on my experience

working with several e-cigarette manufacturers over the years. The test results are also well within

the tolerances set by the manufacturer of MNGO Stick. Therefore, the MNGO Stick is not

misrepresenting the amount of nicotine in their product using the current industry labeling norms.

26. Based on my experience, consumers are not confused when using a product having 5.37%

or 5.38% nicotine which is advertised as 6% nicotine. First, the product does not exceed 6%

nicotine, and thus it does not confuse the user into potentially consuming too much nicotine.

Second, the actual concentration is within an acceptable range of the advertised concentration.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and

correct. Executed this 15th day of April 2021 at Alamo, CA.

Manoj Misra, Ph.D.

EXHIBIT A

MANOJ MISRA, Ph.D.

Mobile: (919) 608-2087 E-mail: m.misra@hotmail.com

LinkedIn: https://www.linkedin.com/in/manoj-misra-ph-d-289b9148/

EXERIENCE HIGHLIGHTS

E-CIGARETTE

- Five years of professional experience in **Product Stewardship**, **Analytical Vapor assessment**, **Pre-clinical Toxicology & Clinical Testing**.
- Conducted health hazard identification and safety assessment of Vaping Device & e-Cigarette liquid formulations including tobacco leaf-extracts, ingredients and components.
- Designed and managed program for human health hazard and safety of e-cigarette product nonconformances & consumer complaints.
- Established program and department of ENDS product pre-clinical toxicological testing including e-liquid formulations, device components safety, aerosol analytical and in vitro and in vivo testing.
- Developed and conducted system biology and "Tox21" toxicological testing for e-cigarette products.
- Planned, conducted and provided the nicotine and aerosol load yields by smoking E-Cigarettes by various vaping topography parameters.
- Designed and conducted the Environmental Vaping Exposure study for E-Cigarettes with CROs to characterize potential secondhand exposure to emissions from smokers of E-Cigarettes
- Conducted nicotine pharmaco-kinetics (PK) and e-cigarette exposure biomarkers studies at CROs
- Project management for study design and development with CRO including project development, timelines, milestones, deliverables, report.
- Coordination and communication between Technology Development, Analytical Testing, and Toxicology & Life Sciences.

CONVENTIONAL CIGARETTE

- Seventeen year of professional experience in **Product Stewardship**, **Risk and Hazard Assessment**, **Preclinical Toxicological Testing**, and **Research**.
- Developed a "Product Stewardship Plan & Process" for pre-clinical studies
- Ten years of GLP toxicological smoke inhalation experience in various laboratory animal models
- Developed a "Roadmap for *In vitro* Toxicological Testing" for R&D.
- Over fifteen years of professional experience in cigarette prototype and product ingredients, non-tobacco materials and packaging safety and risk assessment.
- Led "Safety Evaluation and Advisory Committee" (SEAC) as chairman. Evaluated, monitored and addressed complex toxicological and biological issues related to the hundreds of ingredients and materials used in the production of the company's products. Provided the company with reviews, opinions and conducted non-clinical toxicological studies to facilitate the safe use of compounds.
- Provided scientifically-based documented decision to assurance that the components, designs, manufacturing processes, and final products do not increase the inherent risk of smoking through "Product Stewardship Committee" (PSC).

- Provided recommendations and decisions to assure to minimize the risk on research activities conducted by or through the Company using human subjects in internal and external smoking panels, environmental exposures and clinical studies through "Review Board".
- Led "**Toxicological Testing Program**" for 10 years and provided literature reviews, planned, coordinated, and conducted several *in vitro* and *in vivo* short- and long-term toxicological studies in-house and CROs laboratories.
- Led the "Low Ignition Propensity" (LIP) program in planning, coordinating and execution of toxicological safety studies in-house and with CROs.
- Led communication between product development, CROs, & senior management for all toxicological studies.
- Developed the whole smoke co-culture lung inflammation model for realistic human smoking conditions *in vitro*.
- Led the *in vitro* "Biomarker Development" program related to model smoking related COPD, CVD and cancer diseases.
- Managed operating budget of about \$ 2 million yearly for studies in-house and at CROs.
- Published 20 scientific publications/ abstracts on tobacco research.
- Presented/participated in 26 scientific presentations tobacco research, ingredient and product testing in national and international scientific conferences.
- Communicated with scientific and regulatory agencies CTP-FDA, NCTR-FDA, EPA, NIEHS, etc.
- Worked with several CROs like, Covance, BioReliance, IITRI, Arista Labs, LabStat, Celerion, etc.

REGULATORY & SCIENTIFIC AFFAIRS

- US-PMTA and Global regulatory product toxicological & safety requirements compliance for ENDS product application and launch.
- Preparation of safety profile documents of cigarette non-combustion zone materials for FDA response.
- Participated in preparation of documents for industry TPSAC response team, e.g., menthol, biomarkers.
- Preparation of toxicological profile documents of ingredients and products.
- Experience and/or knowledge of CORESTA, GLP, OECD, ICH and FDA-ENDS guidelines.

EDUCATION

Ph.D. Toxicology, Industrial Toxicology Research Center (ITRC), India

M.S. Inorganic Chemistry, Lucknow University, India

B.S. Chemistry, Zoology and Botany, Lucknow University, India

CHRONOLOGY OF EMPLOYMENT

Present

Principal, Misra Toxicology Services, LLC

Provide product stewardship services for ENDS product (Pod, device and e-liquid formulation) including gap analysis, study design, and study placements for analytical, GLP non- and pre-clinical toxicological testing, environmental exposure and conduct risk assessment of ingredients, flavors, devices, prototypes, and commercial products. In

addition, Also provide ENDS product quality support for contract manufacturing assessment for product safety to minimize non-conformance incidents.

August 2019- Nov. 2019 Director, Product Integrity & Regulatory Toxicology

Established ENDS commercial product health and safety assessment of manufacturing non-conformances and consumer complaints. ENDS device and components safety evaluation. Ensuring US-PMTA and global regulatory requirements environmental and toxicological testing.

August 2017-July 2019 Head of Toxicology & Quality Manager, JUUL Labs., Inc.

Toxicological Hazard Assessment of product ingredients, device and final product; In Vitro Toxicology Testing, design, Data Interpretation, Analysis, Report preparation- Pre- and non-clinical GLP; Regulatory Toxicological Support; Regulatory engagements with Compliance.

Oct. 2016 - July 2017 Head of Toxicology & Quality Manager, PAX Labs., Inc.
Toxicological Risk Assessment of product ingredients, device and final product; Inhalation
Toxicology Testing design, Placement, Data Interpretation, Analysis, Report preparation- Preand non-clinical GLP; Regulatory Toxicological Support; Regulatory engagements with
Compliance and FDA-CTP; PMTA package preparation.

Nov. 2015 - Oct. 2016 Principal, Misra Toxicology Services, LLC

Toxicology Testing Placement, Data Interpretation, Analysis, Report preparation on various areas: Regulatory Toxicological Support; Pre- and non-clinical GLP toxicological Testing; Inhalation toxicology; Biomarker Development -genomics, proteomics, metabolomics; COPD, CVD, Cancer.

June 2015-Oct. 2015 Sr. Toxicologist, ITG Brands Company, Greensboro, NC

Accountable for product formulation, ingredients, and risk and safety assessment while conducting pre-clinical toxicity testing. Accomplished project planning, budgeting, execution, updates, and all deliverables.

- Achieved toxicological risk assessment of various components of product by preparing ingredients and product toxicological documents for regulatory agencies.
- Served as project leader for aerosol-mediated oxidative stress / damage, 3-D model development in vitro, Biomarkers development in vitro, and role of biological antioxidant system in smoke-induced alterations by developing lung physiological model for high-throughput screening and aerosol co-culture lung inflammation model for realistic human exposure conditions.

Nov. 1997 - June 2015

Manager
Senior Toxicologist
Research Biologist,
Life Sciences/Toxicology, Scientific Affairs
Lorillard Tobacco Company, Greensboro, NC

- Professional experience in conventional cigarette & e-liquid and flavors risk assessment-Product Stewardship, Analytical Vapor assessment, Preclinical Toxicology Testing.
- Conducted health hazard identification and safety assessment of tobaccos, ingredients & Vaping Device E-Cigarette liquid formulations including tobacco leaf-extracts, ingredients and components through Lorillard "Product Stewardship Committee" and "Lorillard Review Board" (LRB).
- Developed a "Roadmap for *In vitro* Toxicological Testing" for R&D.
- Planned, conducted and provided the vaping device aerosol carbonyl formation by smoking several E-Cigarette liquid formulations.
- Planned, conducted and provided the analytical nicotine and aerosol load yields by smoking E-Cigarettes by various vaping topography parameters like, puff volume, puff duration, and puff interval.
- Designed, planned, conducted and provided the *in vitro* toxicology study on E-Cigarette liquid formulation, pad-collected aerosol and whole fresh aerosol toxicological assessment *in vitro*.
- Designed and conducted the Environmental Vaping Exposure study for E-Cigarettes with CROs to characterize potential secondhand exposure to emissions from smokers of E-Cigarettes
- Participated in a clinical study design and development with CRO for nicotine pharmacokinetics & e-cigarette exposure biomarkers
- Project Management: Project development, timelines, milestones, deliverables, report
- Coordination and communication between Technology Development, Analytical Testing, and Life Sciences
- Led communication between product development, CROs, & senior management for all non-clinical toxicological studies.
- Developed the whole smoke co-culture lung inflammation model for realistic human smoking conditions *in vitro*.
- Led the *in vitro* "Biomarker Development" program related to model smoking related COPD, CVD and cancer diseases.
- Published scientific publications/ abstracts on tobacco/e-cig. research.
- Presented/participated scientific presentations tobacco research, ingredient and product testing in national and international scientific conferences.
- Communicated with scientific and regulatory agencies CTP-FDA, NCTR-FDA, EPA, NIEHS, etc.
- Worked with several CROs like, Covance, BioReliance, IITRI, Arista Labs, LabStat, Celerion, etc.
- Preparation of safety profile documents of cigarette non-combustion zone materials for FDA response.
- Participated in preparation of documents for TPSAC response team, e.g., menthol, biomarkers.
- Preparation of toxicological profile documents of ingredients for product stewardship process with Imperial Tobacco Product Science.
- Experience and/or knowledge of CORESTA, GLP, OECD, ICH and FDA-Redbook guidelines.
- Coordination and management of tobacco product ingredients regulatory submission for federal (HHS) and state (MA & TX) governments.
- Led "Lorillard Testing Program" for 10 years and provided literature reviews, planned,

- coordinated, and conducted several non-clinical *in vitro* and *in vivo* short- and long-term toxicological studies in-house and CROs laboratories.
- Led the "Low Ignition Propensity" (LIP) program for Lorillard in planning, coordinating and execution of non-clinical toxicological safety studies in-house and with CROs.
- Led the Spearmint flavor toxicological safety project for Lorillard in planning, coordinating and execution both in-house and with CROs.
- Managed operating budget of about \$ 2 million yearly for studies in-house and at CROs.
- Projects preparation and presentation to management.
- Project planning, timelines, budget, priority research paths, personnel/group management
- **Testing Program:** Program Leader. Literature review, planning, coordinating, and conducting the program in-house and/or contract laboratories. These studies range from in vitro toxicological tests to in vivo short- and long-term tests in animal models. Adapt CFR, FDA, and NTP databases and guidelines for testing program.
- Safety Evaluation and Advisory Committee (SEAC): Serve as "Chairman". This committee routinely meets, monitor and address the complex toxicological and biological issues related to the ingredients and materials used in the production of the company's products. As necessary, it provides the company with periodic reviews, opinions or recommendations related to toxicological and chemical data regarding the safe use of these compounds.
- **Supervision** of Toxicology/Life Sciences group including Toxicologists (2), Senior Research Biologists (1), Research Biologists (2), and Technicians (3).

Senior Scientist, Cellular and Molecular Toxicology, ManTech Environmental Technology, Inc., 2
Triangle Drive, Research Triangle Park, NC 27709
(In vitro and in vivo toxicological studies for drug safety, testing, and chemoprevention, Cellular and Molecular biology)

Research Associate, Department of Chemistry, Dartmouth College, Hanover,
New Hampshire 03755. (Non-clinical Biochemical and Molecular Toxicology)

Visiting Fellow, Laboratory of Comparative Carcinogenesis, National Cancer Institute-Frederick Cancer Research & Development Center, Frederick, MD 21701. (Non-clinical *in vitro* and *in vivo* Biochemical/genotoxicology, and Carcinogenesis)

HONORS, PROFESSIONAL MEMBERSHIP & SCIENTIFIC RECOGNITION

- Member of American College of Toxicology (ACT), USA, 2010-present
- Member of Society of Toxicology (SOT), USA, 2005-present
- Cardiovascular Toxicology Specialty Section-SOT, 2005-present
- In Vitro Specialty Section-SOT, 2005-present
- Inhalation Specialty Section-SOT, 2005-present
- Mixtures Specialty Section-SOT, 2005-present
- Regulatory and Safety Evaluation Specialty Section-SOT, 2005-present
- Risk Assessment Specialty Section-SOT, 2005-present

- Member, Product Stewardship Committee (PSC), Lorillard Company, 2005-2015
- Member, Lorillard Review Board (LRB), Lorillard Company, 2005-2015
- Chair, Safety Evaluation and Advisory Committee (SEAC), Lorillard Company, 2000-2005
- Member of Animal Use and Care committee, ManTech International, 1995-1996
- Member of American Association for Cancer Research (AACR), USA, 1995-1997
- National Cancer Institute Fogarty Fellow Training Award, USA, 1988- 1991
- North Dakota State University Research Fellowship, USA, 1987-1988

PUBLICATIONS & ABSTRACTS

See Attachment A

SCIENTIFIC MEETINGS / PRESENTATIONS

See Attachment B

Attachment A

PUBLICATIONS & ABSTRACTS

- 1. Behari, J. R., Dwivedi, P. P., Misra, M., and Srivastava R. C. Kinetics of nickel binding in hepatic and renal cytosol of NiCl₂ treated rats. *Biol. Trace Element Res.*, 6: 463-467, 1984.
- 2. Dwivedi, P. P., Behari, J. R., Misra, M., and Srivastava, R. C. Kinetics and dose dependence of glutathione, glutathione-S-transferase and phosphoglucomutase in liver and kidney of nickel treated partially hepatectomized rats. *Ind. Health*, 23: 269-277, 1985.
- 3. Misra, M., Athar, M., Chandra, S., Hasan, S. K., and Srivastava, R.C. Pharmacokinetics and metabolic disposition of nickel in poisoned rats-effect of chelating drugs. *Chemosphere*, 16(1): 259-267, 1987.
- 4. Athar, M., Misra, M., and Srivastava, R. C. Evaluation of chelating drugs on the toxicity, excretion and distribution of nickel in poisoned rats. *Fund. Appl. Toxicol.*, 9(1): 26-33, 1987.
- 5. Srivastava, R.C., Gupta, B.N., Athar, M., Behari, J.R., Dwivedi, R.S., Hasan, S.K., Singh, A., Misra, M., and Ray, P.K.: Effect of exposure to toxic gas on the population of Bhopal, Part III Assessment of toxic manifestation in humans-hematological and biochemical studies. *Ind. J. Exp. Biol.*, 26(3): 165-172, 1988.
- 6. Misra, M., Athar, M., Hasan, S. K., and Srivastava, R. C. Alleviation of nickel induced biochemical alterations by chelating agents. *Fund. Appl. Toxicol.*, 11(2): 285-292, 1988.
- 7. Misra, M., Athar, M., Hasan, S. K., and Srivastava, R. C. Comparative effects of chelating drugs on trace metal and biochemical alterations in the rat. *Bull. Environ. Contam. Toxicol.*, 41: 172-184, 1988.
- 8. Misra, M., and Schnell, R.C.: Effect of selenium on allyl alcohol hepato-toxicity in the rat. *The Toxicologist*, 9, 27, 1989.
- 9. Rodriguez, R.E., Misra, M., North, S.L. and Kasprzak, K.S.: Nickel interaction with catalase and superoxide dismutase in the Fischer rat. *The Toxicologist*, 10, 21, 1990.
- 10. Kasprzak, K.S., Diwan, B.A., Konishi, N., Misra, M., and Rice, J.M. Initiation by nickel acetate and promotion by sodium barbital of renal cortical epithelial tumors in male F344 rats. *Carcinogenesis*, 11(4): 647-652, 1990.
- 11. Rodriguez, R.E., Misra, M., and Kasprzak, K.S. Effects of nickel on catalase activity in vitro and in vivo. *Toxicology*, 63(1): 45-52, 1990.
- 12. Misra, M., Rodriguez, R.E. and Kasprzak, K.S. Nickel-induced lipid peroxidation in the rat: correlation with nickel effects on antioxidant defense systems. *Toxicology*, 64(1):1-17, 1990.

- 13. Misra, M., Rodriguez, R.E., North, S.L. and Kasprzak, K.S.: Correlation between nickel interaction with glutathione and related enzymes and lipid peroxidation in the Fischer rat. *The Toxicologist*, 10, 158, 1990.
- Rodriguez, R.E., Misra, M., North, S.L. and Kasprzak, K.S.: Nickel effect on catalase, glutathione peroxidase and superoxide dismutase in C3H and C57BL mice. *Proceedings of AACR*, 31, 145, 1990.
- 15. Misra, M., Rodriguez, R.E., North, S.L. and Kasprzak, K.S.: Effect of nickel on lipid peroxidation, glutathione, and related enzymes in different strains of mice. *Proceedings of AACR*, 31, 146, 1990.
- 16. Kasprzak, K.S., Misra, M., Rodriguez, R.E., and North, S.L.: Nickel-induced oxidation of renal DNA guanine residues in vivo and in vitro. *The Toxicologist*, 11(1), 233, 1991.
- 17. Wink, D.A., Kasprzak, K.S., Maragos, C.M., Misra, M., Dumans, T.M., Andrews, A.W., and Keefer, L.K.: DNA base deamination ability and genotoxic potential of nitric oxide. *Proceedings of AACR*, 32, 113, 1991.
- 18. Rodriguez, R.E., Misra, M., North, S.L., and Kasprzak, K.S. Nickel-induced lipid peroxidation in the liver of different strains of mice: correlation with nickel effects on catalase, superoxide dismutase, glutathione peroxidase, glutathione and related enzymes. *Toxicol. Lett.*, 57(3), 269-281, 1991.
- 19. Misra, M., Rodriguez, R.E., North, S.L., and Kasprzak, K.S. Nickel-induced renal lipid peroxidation in different strains of mice: concurrence with nickel effect on antioxidant systems. *Toxicol. Lett.*, 58(2):121-133, 1991.
- 20. Wink, D.A., Kasprzak, K.S., Maragos, C.M., Misra, M., Dunams, T.M., Elespuru, R.K., Cebula, T.A., Koch, W.H., Andrews, A.W., Allen, J.S., and Keefer, L.K. DNA deamination ability and genotoxicity of nitric oxide and its progenitors. *Science*, 254(5034): 1001-1003, 1991.
- 21. Datta, A.K., Misra, M., North, L.S., and Kasprzak, K.S. Enhancement by nickel(II) and L-histidine of 2'-deoxyguanosine oxidation with hydrogen peroxide. *Carcinogenesis*, 13(2): 283-287, 1992.
- 22. Kasprzak, K.S., Diwan, B., Rice, J.M., Misra, M., Riggs, C.W., Olinski, R., Dizdaroglu, M. Nickel(II)-mediated oxidative DNA base damage in renal and hepatic chromatin of pregnant rats and their fetuses. Possible relevance to carcinogenesis. *Chem. Res. Toxicol.*, 5(6): 809-815, 1992.
- 23. Misra, M., Olinski, R., Dizdaroglu, M., and Kasprzak, K.S. Enhancement by L-histidine of nickel(II)-induced DNA-protein cross-linking and oxidative DNA base damage in the rat kidney. *Chem. Res. Toxicol.*, 6(1): 33-37, 1993.

- 24. Misra, M. and Wetterhahn, K.E: The effect of dietary ascorbic acid and L-BSO on Cr (VI)-induced damage in mutant rat unable to synthesize ascorbic acid. *Proceedings of AACR*, 35, 140, 1994.
- 25. Misra, M. and Wetterhahn, K.E: Role of glutathione on chromium (VI)-induced DNA damage in liver and red blood cells of 14-day chick embryos. *Proceedings of AACR*, 35, 131, 1994.
- 26. Alcedo, J., Misra, M., Hamilton, J.W., and Wetterhahn, K.E. The genotoxic carcinogen chromium(VI) alters the metal-inducible expression but not the basal expression of the metallothionein gene in vivo. *Carcinogenesis*, 15(5), 1089-1092, 1994.
- 27. Misra, M., Alcedo, J., and Wetterhahn, K.E. Two pathways for chromium (VI)-induced DNA damage in 14-day chick embryos: Cr-DNA binding in liver and 8-Oxo-2'-deoxyguanosine in red blood cells. *Carcinogenesis*, 15(12): 2911-2917, 1994.
- 28. Rodriguez, R.E., Misra, M., Diwan, B.A., Riggs, C.W. and Kasprzak, K.S.: Relative susceptibilities of C3H, B6C3F1, and C57BL mice to carcinogenesis and acute toxicity of nickel subsulfide: do they depend on antioxidant defense systems? *Proceedings of AACR*, 36, 125, 1995.
- 29. Misra, M., Alcedo, J., and Wetterhahn, K.E.: Chromium (VI)-induced DNA damage affects hormone- and metal-inducible gene expression in chromium(VI)-treated cultured rat FAO cells. *The Toxicologist*, 15(1), 56, 1995.
- 30. Wetterhahn, K. E., Stearns, D. M., Misra, M., Giangrande, P. H., Phieffer, L. S., Kennedy, L. J., and Courtney, K. D. "The Role of Ascorbate in Metabolism and Genotoxicity of Chromium (VI)." Genetic Response to Metals: B. Sarkar (ed.), Marcel Dekker, Inc., New York, 1995.
- 31. Gupta, S., Behari, J.R., Srivastava, S., Misra, M., Srivastava, R.C. Efficacy of liposome encapsulated triethylenetetraamine hexaacetic acid (TTHA) against cadmium intoxication: Role of lipid composition, *Industrial Health*, 33 (2), 83-88, 1995.
- 32. Rodriguez, R.E., Misra, M., Diwan, B.A., Riggs, C.W. and Kasprzak, K.S.: Relative susceptibilities of C57BL/6, (C57BL/6 x C3H/He)F1, and C3H/He mice to acute toxicity and carcinogenicity of nickel subsulfide. *Toxicology*, 107: 131-140, 1996.
- 33. Sharma, S., Misra, M., Wilkinson, B., and Steele, V.E.: Development of biomarkers for risk assessment using a primary tracheal epithelial cell system. *The Toxicologist*, 36(1)2, 6, 1997.
- 34. Misra, M., Behari, J.R. Effect of liposome-encapsulated meso-2, 3-dimercaptosuccinic acid on mice exposed to lead through drinking water. *Bollettino Chimico Farmaceutico* 136 (10), 611-614, 1997.
- 35. Manoj Misra, J.D. Heck, C.L. Gaworski, N. Rajendran, and R.L. Morrissey: Diammonium phosphate employed as a cigarette ingredient: 13-week cigarette smoke inhalation study in the rat.

- 36. Manoj Misra, Robert D. Leverette, Jonathan T. Hamm, Melanee B. Bennett, J. Daniel Heck, R. Morrissey, Narayanan Rajendran: Toxicological evaluation of a cigarette paper with reduced ignition propensity: *in vitro and in vivo* tests. *The Toxicologist*, 84 (S-1), 1186, 2005.
- 37. J.T. Hamm, S.F. Yee, N. Rajendran, R. L. Morrissey and M. Misra. Focal Proliferative Lesions in A/J Mouse Lung Following 5-Month Exposure to Mainstream Cigarette Smoke. *The Toxicologist*, 84 (S-1), 923, 2005.
- 38. Robert D Leverette, Melanee B. Bennett, Jonathan T. Hamm, Manoj Misra, Suryanarayana V. Vulimiri, and Simon F. Yee. The effect of puff volume on the specific activity of cigarette smoke condensate as measured in the AMES assay. *The Toxicologist*, 84 (S-1), 2229, 2005.
- 39. S. F. Yee, M. Misra, R.D. Leverette, S.V. Vulimiri, J. D. Heck, N. Rajendran, and J.T. Hamm. Differentiating initiating from promoting effects of cigarette mainstream smoke in the production of lung tumors in a mouse inhalation bioassay. *The Toxicologist*, 84 (S-1), 1517, 2005.
- 40. Manoj Misra, Robert D. Leverette, Jonathan T. Hamm, Narayanan Rajendran. Toxicological evaluation of spearmint oil added to tobacco: *in vitro* and *in vivo* tests. *The Toxicologist*, 90 (S-1), 2338, 2006.
- 41. Hamm, J.T., Yee S., Rajendran N., Morrissey R.L., Richter S.J. and Misra M. Histological alterations in male A/J mice following nose-only exposure to tobacco smoke. *Inhal. Toxicol.* 19(5), 405-418. 2007.
- 42. Leverette, R. D., Hamm, J. T, Misra, M. and Middleton, D. C. Effect of cigarette filter ventilation on cytotoxicity, mutagenicity, inflammation and free radicals of smoke particulate matter. *The Toxicologist*, 102 (S-1), 1684, 2008.
- 43. S. V. Vulimiri, M. Misra, J. T. Hamm and A. Berger. Effect of mainstream cigarette smoke Gas/vapor phase and wet total particulate Matter on the metabolic pathways of human Lung epithelial cells: the 'metabolomic' Approach. *The Toxicologist*, 102 (S-1), 907, 2008.
- 44. Suryanarayana V. Vulimiri, Manoj Misra, Jonathan T. Hamm, Matthew Mitchell and Alvin Berger. Effects of Mainstream Cigarette Smoke on the Global Metabolome of Human Lung Epithelial Cells. *Chem. Res. Toxicol.*, 22 (3), pp 492–503, 2009.
- 45. M. Misra, R.D. Leverette, J.T. Hamm, and S.V. Vulimiri. *In vitro* toxicological evaluation of cigarette smoke particulate matter: Effect of dimethyl sulfoxide (DMSO) as solvent. *Beiträge Zur Tabakforschung International*. 24, 2–9, 2010.
- 46. Charleata A. Carter and Manoj Misra. Effect of short-term cigarette exposure on Fisher 344 rats and selected lung proteins. *Toxicologic Pathology*, 38(3), 402-415, 2010.

- 47. Charleata A. Carter and Manoj Misra. Proteomic analysis of mainstream cigarette smoke-exposed Fisher rat noses in a short-term study. *The Toxicologist*, 120 (S-2), 513, 2011.
- 48. M. Misra and D. Ergle. Urinary 8-oxo-deoxyguanosine in smokers: Associations with race, sex, and menthol smoking. *The Toxicologist*, 120 (S-2), 1288, 2011.
- 49. Charleata A. Carter, Manoj Misra, and Steven Pelecht. Proteomic analysis of lung lysate from short-term exposure of Fisher 344 rats to cigarette smoke. *J. of Proteome Res.*, 10 (8), 3720-3731, 2011.
- 50. Manoj Misra and William Polk. Development of an *in vitro* whole smoke co-culture model of human smoking conditions. *Int. J. Toxicology*, 31(1), 118, 2011.
- 51. Charleata A. Carter, Manoj Misra, and Robert R. Maronpot. Morphologic and protein alterations in fisher rat trachea exposed to mainstream cigarette smoke. *Int. J. Toxicology*, 31(1), 118, 2011.
- 52. Charleata A. Carter, Manoj Misra, and Robert R. Maronpot. Tracheal Morphologic and Protein Alterations Following Short-Term Cigarette Mainstream Smoke Exposure to Rats. *J. Toxicol Pathol.* 25(3): 201–207, 2012 http://globalmedicaldiscovery.com/page/3/
- 53. Nancy Harris, Charleata Carter, Manoj Misra, and Robert Maronpot. Immunohistochemistry on Decalcified Rat Nasal Cavity: The Trials and Success. *J. Histotechnology*, 36(3), 92-99, 2013.
- 54. R. Leverette, M. Misra, B. T. Cooper and M. B. Bennett. Potential Toxicity of Electronic Cigarette Liquids and Aerosols As Measured by Four *In Vitro* Assays. *The Toxicologist*, 138(1), 1015, p. 264, 2014.
- 55. Manoj Misra, Robert D. Leverette, Bethany T. Cooper, Melanee B. Bennett and Steven Brown. Comparative toxicity profile of electronic and tobacco cigarette, smokeless- & nicotine replacement therapy products: e-Liquids, Extracts and Collected Aerosols. Submitted in *Int. J. Environm. Res. Public Health*, 2014.
- 56. Edward A. Robinson, Robert D. Leverette, and Manoj Misra. Evaluation of the Potential for Second-hand Exposure to E-cigarette Aerosol in an Office Environment. *Manuscript in preparation*.
- **57.** R. Leverette and M. Misra. Comparative *In Vitro* Toxicity Profile of Electronic and Tobacco Cigarettes: Whole Smoke and Whole Aerosol Exposures. *Manuscript in preparation*.

Attachment B

SCIENTIFIC MEETINGS / PRESENTATIONS

- 1. Misra, M., Dwivedi, P.P., Srivastava, R.C.: Role of ionophores in nickel intoxication. Society of Biological Chemists, Pune, India, 1983.
- 2. Behari, J.R., Misra, M., Dwivedi, P.P. and Srivastava, R.C.: Binding of 63-Ni in liver and kidney cytosol of 63-NiCl2 treated rats. Society of Biological Chemists, India, 1983.
- 3. Dwivedi, P.P., Misra, M., Behari, J.R. and Srivastava, R.C.: Effect of nickel on hepatic and renal glutathione, glutathione-S-transferase and phosphoglucomutase in partially hepatectomized rats. Society of Biological Chemists, Delhi, India, 1984.
- 4. Misra, M., Dwivedi, P.P., Srivastava, R.C.: Evaluation of novel chelating agents for the selective removal of nickel from the nickel poisoned rats. Society of Biological Chemists, Delhi, India, 1984.
- 5. Behari, J.R., Misra, M., Dwivedi, P.P. and Srivastava, R.C.: Binding of nickel-63 in liver and kidney of sham and partially hepatectomized rats. 'Heavy Metals in the Environment', International Conference, Athens, 1985.
- 6. Misra, M., Parmar, S.S. and Srivastava, R.C.: Transport of nickel across bio-membrane. Asian Congress of Pharmacology, New Delhi, India, 1985.
- 7. Misra, M., Athar, M., Srivastava, R.C.: Kinetics of mobilization of nickel in the rats poisoned with nickel-(II)-chloride. Society of Toxicology, Lucknow, India, 1985.
- 8. Misra, M., Athar, M., Srivastava, R.C.: Alleviation of nickel induced biochemical alteration by chelating agents. Indian Pharmacological Society, Kashmir, India, 1986.
- 9. Misra, M., Srivastava, A. and Katiyar, S.S.: Evaluation of LD-50 and ionophoric potential of some 14-membered cyclic ligands. Annual Convention of Chemists, Tamil Nadu, India, 1986.
- 10. Manoj Misra, National Cancer Institute, Frederick Cancer Research and Development Center, Frederick, MD, 1988, "Nickel: Toxicity and Chelation".
- 11. Misra, M., and Schnell, R.C.: Effect of selenium on allyl alcohol hepato-toxicity in the rat. Society of Toxicology, 28th Annual meeting, Atlanta, Georgia, 1989. *The Toxicologist*, 9, 27, 1989.
- 12. Rodriguez, R.E., Misra, M., North, S.L. and Kasprzak, K.S.: Nickel interaction with catalase and superoxide dismutase in the Fischer rat. Society of Toxicology, 29th Annual Meeting Miami, FL.1990.
- 13. Misra, M., Rodriguez, R.E., North, S.L. and Kasprzak, K.S.: Correlation between nickel interaction with glutathione and related enzymes and lipid peroxidation in the Fischer rat. Society of Toxicology, 29th Annual Meeting Miami, FL. 1990.
- 14. Rodriguez, R.E., Misra, M., North, S.L. and Kasprzak, K.S.: Nickel effect on catalase, glutathione peroxidase and superoxide dismutase in C3H and C57BL mice. American Association for Cancer Research, 81st Annual Meeting Washington D.C. 1990.
- 15. Misra, M., Rodriguez, R.E., North, S.L. and Kasprzak, K.S.: Effect of nickel on lipid peroxidation, glutathione, and related enzymes in different strains of mice. American Association for Cancer Research 81st Annual Meeting, Washington, D.C. 1990.
- 16. Kasprzak, K.S., Misra, M., Rodriguez, R.E., and North, S.L.: Nickel-induced oxidation of renal DNA guanine residues in vivo and in vitro. Society of Toxicology, 30th Annual Meeting, TX, 1991.
- 17. Wink, D.A., Kasprzak, K.S., Maragos, C.M., Misra, M., Dumans, T.M., Andrews, A.W., and Keefer, L.K.: DNA base deamination ability and genotoxic potential of nitric oxide. American

- Association for Cancer Research 82nd Annual Meeting, TX, 1991.
- 18. Manoj Misra University of Toronto, Department of Clinical Biochemistry, Toronto, Canada, 1991, "Nickel-induced biochemical- and geno-toxicity".
- 19. Misra, M., Alcedo, J., Pal, S., and Wetterhahn, K.E: Role of glutathione on toxicity, uptake, and Cr-DNA adduct formation in liver and red blood cells of chromium(VI)-treated 14- and 18-day chick embryos. NUTMEG tenth annual meeting, NH, Nov. 1992.
- 20. Misra, M., Alcedo, J., Pal, S., and Wetterhahn, K.E: Role of glutathione on toxicity, uptake, and Cr-DNA adduct formation in liver and red blood cells of chromium(VI)-treated 14- and 18-day chick embryos. 12th Regional Cancer Research symposium, Vermont Cancer Center, VT, 1992.
- 21. Misra, M. and Wetterhahn, K.E: The effect of dietary ascorbic acid and L-BSO on Cr(VI)-induced damage in mutant rat unable to synthesize ascorbic acid. NUTMEG 11th annual meeting, Woods Hole, MA, 1993.
- 22. Manoj Misra National Center for Toxicological Research, Jefferson, AR, April, 1994, "Metals and oxidative DNA damage".
- 23. Misra, M. and Wetterhahn, K.E: The effect of dietary ascorbic acid and L-BSO on Cr(VI)-induced damage in mutant rat unable to synthesize ascorbic acid. AACR, 85th annual meeting, San Francisco, CA, 1994.
- 24. Misra, M. and Wetterhahn, K.E: Role of glutathione on chromium(VI)-induced DNA damage in liver and red blood cells of 14-day chick embryos. AACR, 85th annual meeting, San Francisco, CA,1994.
- 25. Wetterhahn, K. E., Stearns, D. M., Misra, M., Giangrande, P. H., Phieffer, L. S., Kennedy, L. J., and Courtney, K. D.: The Role of Ascorbate in Metabolism and Genotoxicity of Chromium(VI). First International symposium on "Metals and Genetics", Toronto, Canada, May,1994.
- 26. Posewitz, M., Haleblian, G., Roy, J., Bennett, L., Misra, M., Dudek, E., Wetterhahn, K.E., and Wilcox, D.: Role of metallothionein in Ni and Cr carcinogenesis. First International symposium on "Metals and Genetics", Toronto, Canada, May,1994.
- 27. Misra, M., Alcedo, J., and Wetterhahn, K.E.: Chromium(VI)-induced DNA damage affects hormone- and metal-inducible gene expression in chromium(VI)-treated cultured rat FAO cells. Society of Toxicology, 34th Annual Meeting, MD, 1995.
- 28. Rodriguez, R.E., Misra, M., Diwan, B.A., Riggs, C.W. and Kasprzak, K.S.: Relative susceptibilities of C3H, B6C3F1, and C57BL mice to carcinogenesis and acute toxicity of nickel subsulfide: do they depend on antioxidant defense systems? AACR, 86th annual meeting, Toronto, Ontario, Canada, 1995.
- 29. Sharma, S., Misra, M., Wilkinson, B., and Steele, V.E.: Development of biomarkers for risk assessment using a primary tracheal epithelial cell system. Society of Toxicology Annual Meeting, OH, 1997.
- 30. Manoj Misra, J.D. Heck, C.L. Gaworski, N. Rajendran: Toxicologic evaluation of diammonium phosphate added to cigarette tobacco and reconstituted leaf: 13-week smoke inhalation studies in rats. 55th TSRC meeting, Greensboro, NC, Symposium Proceedings, 55, 30, 2001.
- 31. Manoj Misra, J.D. Heck, C.L. Gaworski, N. Rajendran, and R.L. Morrissey: Diammonium phosphate employed as a cigarette ingredient: 13-week cigarette smoke inhalation study in the rat. Society of Toxicology Annual Meeting, Nashville, TN, 2002.
- 32. Simon F. Yee, Manoj Misra, Robert D. Leverette, Suryanarayana V. Vulimiri, J. Daniel Heck, Narayanan Rajendran, and Jonathan Hamm: Differentiating initiating from promoting effects of cigarette mainstream smoke in the production of lung tumors in a mouse inhalation bioassay. 58th TSRC meeting, Symposium Proceedings, 58, 58, 2004.

- 33. Robert D. Leverette, Melanee B. Bennett, Jonathan C. Hamm, Manoj Misra, Suryanarayana V. Vulimiri, and Simon F. Yee: Comparison between Ames and Ames IITM bacterial mutagenicity assays with mainstream smoke particulate matter from three different cigarettes. 58th TSRC meeting, Symposium Proceedings, 58, 64, 2004.
- 34. Manoj Misra, Robert D. Leverette, Jonathan T. Hamm, Melanee B. Bennett, J. Daniel Heck, R. Morrissey, Narayanan Rajendran: Toxicological evaluation of a cigarette paper with reduced ignition propensity: in vitro and in vivo tests. 44th Society of Toxicology Annual Meeting, New Orleans, 2005.
- 35. J.T. Hamm, S.F. Yee, N. Rajendran1, R. L. Morrissey and M. Misra. Focal Proliferative Lesions in A/J Mouse Lung Following 5-Month Exposure to Mainstream Cigarette Smoke. 44th Society of Toxicology Annual Meeting, New Orleans, 2005.
- 36. Robert D Leverette, Melanee B. Bennett, Jonathan T. Hamm, Manoj Misra, Suryanarayana V. Vulimiri, and Simon F. Yee. The effect of puff volume on the specific activity of cigarette smoke condensate as measured in the AMES assay. 44th Society of Toxicology Annual Meeting, New Orleans, 2005.
- 37. S. F. Yee, M. Misra, R.D. Leverette, S.V. Vulimiri, J. D. Heck, N. Rajendran, and J.T. Hamm. Differentiating initiating from promoting effects of cigarette mainstream smoke in the production of lung tumors in a mouse inhalation bioassay. 44th Society of Toxicology Annual Meeting, New Orleans, 2005.
- 38. Manoj Misra, Robert D. Leverette, Jonathan T. Hamm, Narayanan Rajendran. Toxicological evaluation of spearmint oil added to tobacco: *in vitro* and *in vivo* tests. Society of Toxicology Annual Meeting, San Diego, 2006.
- 39. Leverette, R. D., Bennett, M. B., Misra, M., Hamm, J. T., and Reid, J. R. (2007). The effects of nitric oxide in the *in vitro* toxicity of cigarette smoke condensate. CORESTA, Jeju, South Korea, September 30 October 4.
- 40. M. Misra, J.T. Hamm. Effect of dimethyl sulfoxide as solvent on cigarette smoke particulate matter induced IL-8 release and cytotoxicity in A549 cells. XIth International Congress of Toxicology, July 15-19, 2007, Montréal, Canada.
- 41. Leverette, R. D., Hamm, J. T, Misra, M. and Middleton, D. C. (2008). Effect of cigarette filter ventilation on cytotoxicity, mutagenicity, inflammation and free radicals of smoke particulate matter.47th Society of Toxicology Meeting, Seattle, WA, March 16 20.
- 42. S. V. Vulimiri1, M. Misra, J. T. Hamm and A. Berger (2008). Effect of mainstream cigarette smoke Gas/vapor phase and wet total particulate Matter on the metabolic pathways of human Lung epithelial cells: the 'metabolomic' Approach. 47th Society of Toxicology Meeting, Seattle, WA, March 16-20.
- 43. Manoj Misra, Charleata A. Carter, Robert D. Leverette. High Content Screening Analysis of Smoke Toxicity in Human Lung A549 Cells Reveals Biomarkers of Oxidative Stress and Damage. 62nd TSRC meeting, Amelia Island, Florida, 2009.
- 44. Charleata A. Carter and Manoj Misra. Proteomic analysis of cigarette smoke-exposed rat lung tissues in a short-term study. 62nd TSRC meeting, Amelia Island, Florida, 2009.
- 45. E.A. Robinson, M. Misra, and J.D. Ergle. Modulating effects of Fe(II), Fe(III) and Quinone/Hydroquinone on Tobacco smoke-mediated Hydrogen Peroxide Formation. 62nd TSRC meeting, Amelia Island, Florida, 2009.
- 46. Manoj Misra, Invited talk "New Frontier in Tobacco Smoke Toxicology: Metabolomics Approach" Practical Applications of Metabolomics Workshop, December 2, 2009, RTP, NC.
- 47. Manoj Misra, Charleata A Carter, Robert D Leverette and Bethany T Smith. High content

- screening of cigarette smoke mediated biomarkers of effect *in vitro*: Tobacco types. 49th Annual Society of Toxicology Meeting, Salt Lake City, UT March, 2010.
- 48. Charleata A. Carter and Manoj Misra. Proteomic screening of cigarette smoke-exposed rat lungs in a short-term study. 49th Annual Society of Toxicology Meeting, Salt Lake City, UT March, 2010.
- 49. Manoj Misra, Charleata A Carter, Robert D Leverette and Bethany T Smith. High content screening of cigarette smoke mediated biomarkers of effect *in vitro*: Tobacco types. 10th CNC-ACS Poster/Vendor Night, Greensboro, NC, April 13th, 2010.
- 50. Charleata A. Carter and Manoj Misra. Proteomic analysis of mainstream cigarette smoke-exposed Fisher rat noses in a short-term study. 50th Annual Society of Toxicology Meeting, Washington D.C., March 6-10, 2011.
- 51. M. Misra and D. Ergle. Urinary 8-oxo-deoxyguanosine in smokers: Associations with race, sex, and menthol smoking. 50th Annual Society of Toxicology Meeting, Washington D.C., March 6-10, 2011.
- 52. Manoj Misra and William Polk. Development of an *in vitro* whole smoke co-culture to model realistic human smoking conditions. American College of Toxicology 32nd Annual Meeting, Arizona, 2011.
- 53. Charleata A. Carter, Manoj Misra, Robert R. Maronpot. Morphologic and protein alterations in fisher rat trachea exposed to mainstream cigarette smoke. American College of Toxicology 32nd Annual Meeting, Arizona, 2011.
- 54. Manoj Misra. Cytotoxic and Inflammatory Effects of Tobacco-Fatty Acids: Comparative Response from Mono- versus Co-cultured Human Lung Cells *In Vitro*. 51st Annual Society of Toxicology Meeting, San Francisco, March 11-15, 2012.
- 55. R. Leverette, M. Misra, B. T. Cooper and M. B. Bennett. Potential Toxicity of Electronic Cigarette Liquids and Aerosols As Measured by Four In Vitro Assays, 53rd Annual Meeting of the Society of Toxicology, Phoenix, Arizona, March 22 26, 2014.
- 56. Manoj Misra, Robert D. Leverette, Bethany T. Cooper, Melanee B. Bennett. Comparative toxicity profile of electronic and tobacco cigarette, smokeless- & nicotine replacement therapy products: e-Liquids, Extracts and Aerosols. 68th TSRC meeting, Charlottesville, VA 2014.
- 57. Robert D. Leverette, Bethany T. Cooper and Manoj Misra. Assessment of two high throughput in vitro methods for the quantification of cigarette smoke induced micronuclei. 69th TSRC meeting, Naples, FL, 2015.
- 58. Manoj Misra, R.D. Leverette, B. T Cooper and, M. B. Bennett. *In vitro* toxicity screening of blu electronic cigarette liquids and implications for human exposure. 69th TSRC meeting, Naples, FL, 2015.

EXHIBIT B



Report No.:A2103342-C01-20 Date: March 11, 2021 Page 1 of 3

Applicant:
Address:

The following sample(s) and sample information was/were submitted and identified by/on the behalf of the client:

Sample Name MNGO, MNGO STICK STRAWBERRY MANGO 6%

Sample Received Date March 10, 2021

Testing Period March 11, 2021

Test Method & Test Result Please refer to following pages.

Test Requested

As specified by client, according to standard AFNOR XP D90-300-2:2015 to test Nicotine contents in the submitted sample(s).

Tested by:

Inve show

Reviewed by:

Approved by:

Date of issue:

ALPHA TESTING

March 11, 2021



Report No.:A2103342-C01-R20 Date: March 11, 2021 Page 2 of 3

Tested Sample/Part Description

Light yellow transparent liquid

Test Result

Nicotine contents

Method: The samples were extracted by ultrasonic extraction with organic solvent, and the extraction solution was filtered and analyzed by GC-FID

Tested Item(s)	CAS No.	Result (mg/g)	MDL (mg/g)
Nicotine	54-11-5	48.9	0.1

Remark: MDL = Method Detection Limit



Report No.:A2103342-C01-R20 Date: March 11, 2021

Page 3 of 3

Reference photo(S)



--- End of report ---

Statement:

- 1. The sample(s) and sample Information was/were provided by the client who should be responsible for the authenticity which ALPHA hasn't verified;
- 2. The result(s) shown in this report refer(s) only to the sample(s) tested;
- 3. Without written approval of ALPHA, this report can't be reproduced except in full.



Report No.:A2103342-C01-21 Date: March 11, 2021 Page 1 of 3

Applicant:
Address:

The following sample(s) and sample information was/were submitted and identified by/on the behalf of the client:

Sample Name MNGO, MNGO STICK BLUEBERRY MANGO 6%

Sample Received Date March 10, 2021

Testing Period March 11, 2021

Test Method & Test Result Please refer to following pages.

Test Requested

As specified by client, according to standard AFNOR XP D90-300-2:2015 to test Nicotine contents in the submitted sample(s).

Tested by:

Arm shar

Reviewed by:

Approved by:

Date of issue:

March 11, 2021



Tested Sample/Part Description

Light yellow transparent liquid

Test Result

Nicotine contents

Method: The samples were extracted by ultrasonic extraction with organic solvent, and the extraction solution was filtered and analyzed by GC-FID

Tested Item(s)	CAS No.	Result (mg/g)	MDL (mg/g)
Nicotine	54-11-5	49.3	0.1

Remark: MDL = Method Detection Limit



Report No.:A2103342-C01-R21 Date: March 11, 2021

Page 3 of 3

Reference photo(S)



--- End of report ---

Statement:

- 1. The sample(s) and sample Information was/were provided by the client who should be responsible for the authenticity which ALPHA hasn't verified;
- 2. The result(s) shown in this report refer(s) only to the sample(s) tested;
- 3. Without written approval of ALPHA, this report can't be reproduced except in full.



Report No.:A2103342-C01-23 Date: March 11, 2021 Page 1 of 3

Applicant:
Address:

The following sample(s) and sample information was/were submitted and identified by/on the behalf of the client:

Sample Name MNGO, MNGO STICK ICE BANANA 6%

Sample Received Date March 10, 2021

Testing Period March 11, 2021

Test Method & Test Result Please refer to following pages.

Test Requested

As specified by client, according to standard AFNOR XP D90-300-2:2015 to test Nicotine contents in the submitted sample(s).

Tested by:

Arme shar

Reviewed by:

Approved by:

Date of issue: March 11, 2021

ALPHA TESTING



Tested Sample/Part Description

Light yellow transparent liquid

Test Result

Nicotine contents

Method: The samples were extracted by ultrasonic extraction with organic solvent, and the extraction solution was filtered and analyzed by GC-FID

Tested Item(s)	CAS No.	Result (mg/g)	MDL (mg/g
Nicotine	54-11-5	48.7	0.1

Remark: MDL = Method Detection Limit



Report No.:A2103342-C01-R23 Date: March 11, 2021

Page 3 of 3

Reference photo(S)



--- End of report ---

Statement:

- 1. The sample(s) and sample Information was/were provided by the client who should be responsible for the authenticity which ALPHA hasn't verified;
- 2. The result(s) shown in this report refer(s) only to the sample(s) tested;
- 3. Without written approval of ALPHA, this report can't be reproduced except in full.

EXHIBIT C

Report No.: A2104135-C01-23



Date: April 13, 2021 Page 1 of 3 Applicant: Address: The following sample(s)and sample information was/were submitted and identified by/on the behalf of the client: Sample Name MNGO, MNGO STICK ICE BANANA 6% Sample Received Date April 12, 2021 Testing Period April 13, 2021 Test Method & Test Result Please refer to following pages. **Test Requested** As specified by client, according to standard AFNOR XP D90-300-2:2015 to test Nicotine contents in the submitted sample(s). Approved by: Tested by: Reviewed by: April 13, 2021 Date of issue:



Report No.:A2104135-C01-R23 Date: April 13, 2021 Page 2 of 3

Tested Sample/Part Description

Light yellow transparent liquid

Test Result

Nicotine contents

Method: The samples were extracted by ultrasonic extraction with organic solvent, and the extraction solution was filtered and analyzed by GC-FID

Tested Item(s)	CAS No.	Result (mg/g)	MDL (mg/g)
Nicotine	54-11-5	49.2	0.1

Remark: MDL = Method Detection Limit



Report No.:A2104135-C01-R23

Date: April 13, 2021

Page 3 of 3

Reference photo(S)



--- End of report ---

Statement:

- The sample(s) and sample Information was/were provided by the client who should be responsible for the authenticity which ALPHA hasn't verified;
- 2. The result(s) shown in this report refer(s) only to the sample(s) tested;
- 3. Without written approval of ALPHA, this report can't be reproduced except in full.

Date: April 13, 2021

Report No.:A2104135-C01-21



Page 1 of 3

Applicant: Address: The following sample(s)and sample information was/were submitted and identified by/on the behalf of the client: Sample Name MNGO, MNGO STICK BLUEBERRY MANGO 6% Sample Received Date April 12, 2021 **Testing Period** April 13, 2021 Test Method & Test Result Please refer to following pages. **Test Requested** As specified by client, according to standard AFNOR XP D90-300-2:2015 to test Nicotine contents in the submitted sample(s). Approved by: Tested by: April 13, 2021 Reviewed by:



Report No.:A2104135-C01-R21 Date: April 13, 2021 Page 2 of 3

Tested Sample/Part Description

Light yellow transparent liquid

Test Result

Nicotine contents

Method: The samples were extracted by ultrasonic extraction with organic solvent, and the extraction solution was filtered and analyzed by GC-FID

Tested Item(s)	CAS No.	Result (mg/g)	MDL (mg/g)	
Nicotine	54-11-5	49.1	0.1	

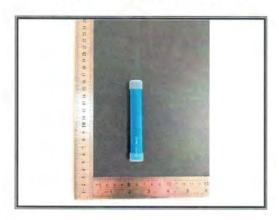
Remark: MDL = Method Detection Limit



Report No.:A2104135-C01-R21 Date: April 13, 2021

Page 3 of 3

Reference photo(S)



--- End of report ---

Statement:

- 1. The sample(s) and sample Information was/were provided by the client who should be responsible for the authenticity which ALPHA hasn't verified;
- 2. The result(s) shown in this report refer(s) only to the sample(s) tested;
- 3. Without written approval of ALPHA, this report can't be reproduced except in full.



Report No.: A2104135-C01-20 Date: April 13, 2021 Page 1 of 3 Applicant: Address: The following sample(s)and sample information was/were submitted and identified by/on the behalf of the client: Sample Name MNGO, MNGO STICK STRAWBERRY MANGO 6% Sample Received Date April 12, 2021 **Testing Period** April 13, 2021 Test Method & Test Result Please refer to following pages. **Test Requested** As specified by client, according to standard AFNOR XP D90-300-2:2015 to test Nicotine contents in the submitted sample(s). Approved by: Tested by: Reviewed by: April 13, 2021



Report No.:A2104135-C01-R20 Date: April 13, 2021 Page 2 of 3

Tested Sample/Part Description

Light yellow transparent liquid

Test Result

Nicotine contents

Method: The samples were extracted by ultrasonic extraction with organic solvent, and the extraction solution was filtered and analyzed by GC-FID

Tested Item(s)	CAS No.	Result (mg/g)	MDL (mg/g)
Nicotine	54-11-5	48.5	0.1

Remark: MDL = Method Detection Limit

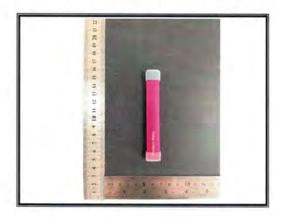


Report No.:A2104135-C01-R20

Date: April 13, 2021

Page 3 of 3

Reference photo(S)



--- End of report ---

Statement:

- The sample(s) and sample Information was/were provided by the client who should be responsible for the authenticity which ALPHA hasn't verified;
- 2. The result(s) shown in this report refer(s) only to the sample(s) tested;
- 3. Without written approval of ALPHA, this report can't be reproduced except in full.

EXHIBIT D



MNGO E-Cigarette BLUEBERRY MANGO Flavor

Finished Product -6%mg/mL Nicotine.

E-Cigarette Finished Product -6% mg/mL BLUEBERRY MANGO

Product Name

MNGO E-Cigarette BLUEBERRY MANGO Flavor - Finished Product -6% mg/mL Nicotine

Finished E-Cigarette

Finished E-Cigarette

Components

Component	ID/Ref
Bulk E-Liquid BLUEBERRY MANGO 6%mg/ml Nicotine Release Specification	Blueberry Mango 6%

Product Specifications

TEST	METHOD	SPECIFICATION LIMITS	
		Lot Release Specification	Stability End-Point Specification
BEELEWAY STREET			
	THE REAL PROPERTY.		
Nicotine Assay	LAB	53 mg/mL (+/- 10%)	53 mg/mL (+ 10% – 35%)
Specific Gravity	USP	1.12 g/mL (+/- 10%)	1.12 g/mL (+/- 15%)
BROWN			

Approvals

Name and Position	Signature	Date	
Hua gan Pan / manger	涨水 走干		
Jun Jun Jungo	AFICA		
		*	



MNGO E-Cigarette ICED BANANA Flavor

Finished Product -6%mg/mL Nicotine.

E-Cigarette Finished Product -6% mg/mL ICED BANANA

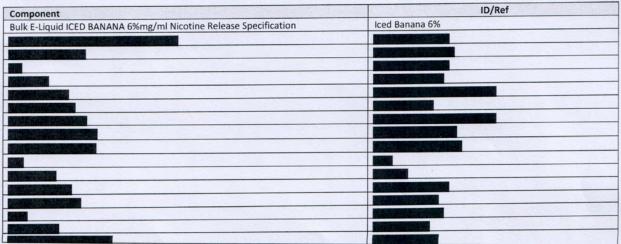
Product Name

MNGO E-Cigarette ICED BANANA Flavor - Finished Product –6% mg/mL
Nicotine

Product Category

Finished E-Cigarette

Components



Product Specifications

TEST	METHOD	SPECIFICATION LIMITS	
		Lot Release Specification	Stability End-Point Specification
		RAY CONTRACTOR OF THE SECOND CONTRACTOR OF THE	
Nicotine Assay	LAB	53 mg/mL (+/- 10%)	53 mg/mL (+ 10% – 35%)
Specific Gravity	USP	1.12 g/mL (+/- 10%)	1.12 g/mL (+/- 15%)
DESCRIPTION OF THE PERSON OF T			
DESCRIPTION OF THE PERSON OF T		KINGGAN	

Approvals

Date



MNGO E-Cigarette STRAWBERRY MANGO Flavor

Finished Product -6%mg/mL Nicotine.

E-Cigarette Finished Product -6% mg/mL STRAWBERRY MANGO

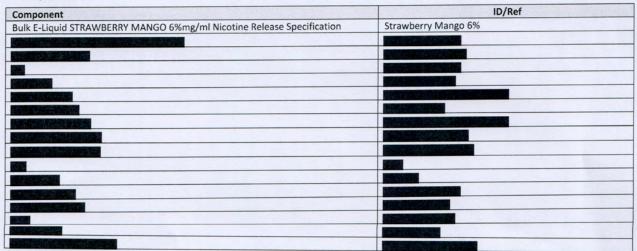
Product Name

MNGO E-Cigarette STRAWBERRY MANGO Flavor - Finished Product –6% mg/mL Nicotine

Product Category

Finished E-Cigarette

Components



Product Specifications

TEST	METHOD	SPECIFICATION LIMITS	
		Lot Release Specification	Stability End-Point Specification
A 2015 S. C. S.	MESE .		
Nicotine Assay	LAB	53 mg/mL (+/- 10%)	53 mg/mL (+ 10% – 35%)
Specific Gravity	USP	1.12 g/mL (+/- 10%)	1.12 g/mL (+/- 15%)

Approvals

Name and Position	Signature	Date	
Huagan Pan/man	ager BAKE7		
	V		

EXHIBIT E

NICOTINE LOSS SUMMARY

INTRODUCTION

In 2016, the Food and Drug Administration (FDA) set the requirements for the manufacture of e-liquids in the United States. This includes standards for the accuracy of labelled nicotine content, quality of ingredients in e-liquid, grade-certified bases for these liquids, and minimum standards for the quality of flavors and colors [FDA 2016, AEMSA 2017].

The nicotine used in e-cigarettes and refill e-liquids is extracted from tobacco, and its purity can vary depending upon manufacturer and grade. The US and European Pharmacopoeias make recommendations for the purity of nicotine intended for pharmaceuticals.

NICOTINE STABILITY AND DEGRADATION FACTORS

Nicotine is a volatile, strongly alkaline, oily liquid, which when pure is colorless but turns yellow on oxidation. It is very hygroscopic and turns brown on exposure to air or light.

Nicotine is susceptible to degradation under hydrolytic, oxidative, thermolytic, and photolytic conditions (Nagwa, 2010).

Upon nicotine degradation, nicotine related degradation products are formed. The major nicotine degradation compounds, Nicotine-N-oxide, nornicotine, mysomine, and cotinine were observed to increase with time during storage and stability studies. The increased levels of these degradation compounds lead to the reduced level of nicotine during storage and stability. The high levels of nicotine-N-oxides are a known oxidation product of nicotine.

Nicotine loss and degradation is common and several known factors play crucial role including the influence of water, heat, light, oxidation by UV light, acids, hydrogen peroxide, chlorine, metals.

Additional factors affecting nicotine stability can range from purity of the original nicotine used in the e-liquids, packaging factors such as oxygen transfer rate, product age, and storage conditions.

To further analyze, when testing for nicotine it is very common to see a drop in nicotine in ENDS devices due to the following conditions:

Confidentiality Statement: Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Chemular, Inc.

- 1. EFFECT OF WATER Due to the hydroscopic nature of vegetable glycerin, it is not uncommon for 5-10%. The primary reason for such observation is that formulations in PG/VG mostly hydrophobic in nature and contain very little water. As formulation age, the hygroscopic nature of PG/VG absorb atmospheric water and play a role in nicotine dilution and some report indicate to play role in oxidation/degradation.
- 2. EFFECT OF LIGHT: Nicotine degradation is about 5% within 10 days.
- 3. EFFECT OF OXIDATIVE ENVIRONMENT (acid/alkaline): Nicotine degradation is about 20% within 10 days.
- 4. EFFECT OF PEROXIDES (H₂O₂): Nicotine degradation is about 15-80% within 1hour. The peroxide like, hydrogen peroxide (H₂O₂) formed by the Fenton chemistry reaction of metal impurities contamination (iron and copper) present in the e-liquid with oxygen and water. H₂O₂ is very potent chemical for nicotine oxidation and degradation. It is known that nicotine is extremely prone for oxidative degradation. The standard oxidative conditions where the production of compounds such as H₂O₂ is studied, a significant nicotine degradation was observed even with few hours of formulation. Various conditions or factors such as water, pH and metals play a major role in the production of oxidative conditions in solution.
- 5. EFFECT OF IMPURITIES: The impurities present in Natural Flavors Compounds (NFCs) such as iron (Fe) play a major role in Fenton chemical reaction which known to product reactive oxygen radicals and H₂O₂.
- 6. EFFECT OF HIGHER TEMPERATURE (manufacturing/storage): Nicotine degradation is about 15% within 10 days. It has been observed that nicotine in solution at 60°C expected to degrade over 15-18% of originally added nicotine after 10 days of formulation as compared to no degradation observed at ambient temp. (25 °C).
- 7. EFFECT OF HIGHER PH: Nicotine degradation is about 13% at 60 °C.
- 8. EFFECT OF MICROBIAL CONTAMINATION (bacterial) can degrade nicotine to product tobacco specific nitrosamines (TSNAs).
- 9. EFFECT OF CHLORINE IN WATER: Significant nicotine degradation has been observed when chlorine is present in the water.
- 10. Nicotine loss through evaporation, adsorption into the container material (cartridge or refill bottle).

Confidentiality Statement: Data and information contained in this document are considered to constitute trade secrets and confidential commercial information, and the legal protections provided to such trade secrets and confidential information are hereby claimed under the applicable provisions of United States law. No part of this document may be publicly disclosed without the written consent of Chemular, Inc.

11. Added nicotine calculations error: Percentage (%), weight/weight (w/w), concentration (mg/mL)

MINIMUM RECOMMENDATIONS:

- 1. Nicotine lot-to-lot variation is minimal evident by COA.
- 2. Important to get ingredient/purity/Impurities information.
- 3. The time gap between the addition of Nicotine in formulation should be minimize and consistent across e-liquids.
- 4. Nicotine should be kept in proper storage condition to minimize artificial degradation (Temp. control, Ar/He Purged; Light protected).
- 5. Temperature control during formulation manufacturing.
- 6. Storage of final formulations in temperature control and light protected area.

REFERENCES

Bansal et. al. A Stability Indicating HPLC Method to Determine Actual Content and Stability of Nicotine within Electronic Cigarette Liquids. Int. J. Environ. Res. Public Health 2018, 15, 1737; doi:10.3390/ijerph15081737.

U.S. Food and Drug Administration. Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS); U.S. Food and Drug Administration: Silver Spring, MD, USA, 2016.

AEMSA 2017. E-liquid Manufacturing Standards Association. Available online: https://www.aemsa.org/ (accessed on 6 March 2017).

Ngwa, G. Forced degradation as an integral part of HPLC stability-indicating method development. Drug Deliv. Technol. 2010, 10, 56–59.

US EPA 2016. Degradation of Nicotine in Chlorinated Water: Pathways and Kinetics. EPA/600/R-16/073 | May 2016 (www.epa.gov/homeland-security-research).